Bayer CropScience

I024202

June 29, 2012

Document Processing Desk 6(a)(2)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: 6(a)(2) Incidents Accumulated for the Month of May 2012

Dear Sir/Madam:

Bayer CropScience
RTP
P. O. Box 12014
RTP, NC 27709
Tel. 919 549-2000

Reportable incidents accumulated for the month of May 2012 for Bayer CropScience and Bayer Environmental Science are attached.

The information with this letter is being submitted to the EPA pursuant to the Agency's interpretation of requirements imposed on registrants by Section 6(a)(2) of FIFRA. This information does not necessarily constitute additional factual information regarding unreasonable adverse effects within the meaning of 6(a)(2). It is being submitted to enable the Agency to make its own assessment of the information.

If you have questions or concerns, please do not hesitate to contact me at any time.

Sincerely,

S. Gerret Van Duyn

Gerret Van Duyn
Compliance Manager
State Regulatory and Documentation Services
919-549-2914

CC: AE Coordinator, CA Department of Pesticide Regulation
Jeanine Broughel, NY Department of Environmental Conservation

/attachment

Personal privacy information

-007

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

Row 1 Administrative Data	Reporter Name [redacted]	Submission date. ***6/29/2012***	Contact person (if different than reporter)	Internal ID ***978240-1***
	Address [redacted]		Address Phone #	
	Incident Status: ***New***	Location and date of incident ***Middleberg, FL USA Chronic: >1 month <= 3 months***	Date registrant became aware of incident. ***05/22/2012***	Was incident part of larger study? ***No***

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) ***72155-80***	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) ***Beta-Cyfluthrin, sodium o-phenylphenate***	A.I. (s)	A.I. (s)
	Product 1 name ***Home Pest plus Germ Killer Indoor & Outdoor Killer RTU (1 Gal)***	Product 2 Name	Product 3 Name
	Exposed to concentrate prior to dilution? ***No***	Exposed to concentrate prior to dilution?	Exposed to concentrate prior to dilution?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? ***No*** Intentional misuse? ***No***	Incident site: (examples include home, yard, school, industrial, nursery/greenhouse, surface water, commercial turf, building/office, forest/ woods, agricultural (specify crop) right-of-way (rail, utility, highway)). ***Own Residence***	Situation (act of using product): (examples include mixing/loading, reentry, application, transportation, repair/maintenance of application equipment, manufacturing/ formulating). ***See Incident Description Notes***
	Applicator certified? ***UNK***		
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff) ***See Incident Description Notes***		

Personal privacy information

Brief description of incident circumstances.

Nordaune, Abby May 22 2012 6:42PM
Hx: [redacted] is calling on behalf of his girlfriend [redacted], her son [redacted], and her son's girlfriend [redacted] Due to the complexity of the case he has somewhat limited / fragmented details of potential exposure histories. He is concerned about the recent use of this product in a camper and his own home and apparent seizure activity several people have had recently.

Caller states that [redacted] sprayed this product 4-5x over a two-week period of time about 2 months ago to the interior of a camper that he is living in. At the time of application, the windows were open in the camper to allow air flow / ventilation. This product was also sprayed twice over a two week period of time to the interior of [redacted] own home as well about 6 weeks ago.

[redacted] reports that [redacted] apparently had 1+ seizures of unknown duration about 1 week ago (on 5/16/2012) and was subsequently seen at a local ER for evaluation. As [redacted] had no history of seizures, he was subsequently admitted to the hospital for evaluation. A CT, MRI and EEG were performed at the time though no specific findings were made. [redacted] was apparently transferred to another local hospital on 5/20/2012 at which time he apparently suffered another seizure at which time was administered a dose of ativan though went on to experience an additional 2 seizure episodes and has subsequently been officially diagnosed with a seizure disorder. [redacted] reports that [redacted] was released from the hospital today (5/22/2012) apparently without any outpatient medication therapy to take and upon returning home, he took shower in the camper and had yet another seizure at home and transported back to the hospital where he is at present.

[redacted] also indicates that his own girlfriend [redacted] apparently suffered a single seizure about 1 month ago of unknown duration. She was seen by a local physician at which time an EEG, MRI and CT scan were performed. Although the test results were "normal" she was diagnosed with epilepsy and started on anti-epileptic drug therapy (Keppra). [redacted] also indicated that [redacted] had a seizure about 5 yrs ago as well though at that time was not started on any drug therapy.

[redacted] also reports that [redacted] had a seizure on 5/14/2012 of an unknown duration. She was seen by a local physician and received an MRI, CT scan and EEG. Results appear to indicate scarring on her frontal lobe and underlying epileptic activity. [redacted] has been started on Keppra. [redacted] reports there is a history of seizures in her family but she has not had them in the past.

[redacted] is most worried about the seizure activity and link with the use of the product.

A: Discussed with SL –

There is no indication that the use of the product is at all linked with the reported health effects; it is difficult to determine that an actual exposure to the product at any concentration has even occurred other than simply residing in a home / structure that product had been sprayed in. Given the low concentration of the AI in product, even in the event that gross misuse of the product had occurred inhalation exposure to the product is not expected to result in such neurological effects and additionally, 2 of the 3 parties involved have at least a vague history of seizure activity in the past that cannot be discounted.

Would encourage anyone affected to continue to follow-up with their primary care providers as directed and if they have specific questions regarding the tox profile of the product, AI etc, please have them call. Provided tele# and case#
****
LeMaster, Steve May 23 2012 10:50AM
notified client

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

Demographic information: Age: ***19 Year(s)*** Sex: ***Male*** Occupation (if relevant) ***NA***	Exposure route: ***Unknown route***	Was adverse effect result of suicide/homicide or attempted suicide/homicide? ***No***	Was protective clothing worn (specify)? ***None Reported***
If female, pregnant? ***NA***	Was exposure occupational? ***Not indicated*** If yes, days lost due to illness: ***NA***	Time between exposure and onset of symptoms: ***>1 month and <=3 months***	
Type of medical care sought: (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient). ***ER/Hospital-admitted***	List signs/symptoms/adverse effects ***Gastrointestinal-Emesis/Vomiting*** ***Neurological-Seizure (multiple/discrete)***		If lab tests were performed, list test names and results (If available, submit reports) ***None Reported***
Exposure data: ***NA*** Amount of pesticide: ***NA*** Exposure duration: ***Chronic: >1 month <= 3 months*** Patient weight: ***Unknown***			
Human severity category: ***HC***			
This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)			
			Internal ID # ***978240-1***

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Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

Row 1 Administrative Data	Reporter Name [redacted]	Submission date. ***6/29/2012***	Contact person (if different than reporter)	Internal ID ***978240-2***
	Address [redacted]		Address	
	Phone # [redacted]		Phone #	
	Incident Status: ***New***	Location and date of incident ***Middleberg, FL USA Chronic: >1 month <= 3 months***	Date registrant became aware of incident. ***05/22/2012***	Was incident part of larger study? ***No***

Row 2 Pesticide(s) Involved	EPA Registration # (Product 1) ***72155-80***	EPA Registration # (Product 2)	EPA Registration # (Product 3)
	A.I. (s) ***Beta-Cyfluthrin, sodium o-phenylphenate***	A.I. (s)	A.I. (s)
	Product 1 name ***Home Pest plus Germ Killer Indoor & Outdoor Killer RTU (1 Gal)***	Product 2 Name	Product 3 Name
	Exposed to concentrate prior to dilution? ***No***	Exposed to concentrate prior to dilution?	Exposed to concentrate prior to dilution?
	Formulation	Formulation	Formulation

Row 3 Incident Circumstances	Evidence label directions were not followed? ***No*** Intentional misuse? ***No*** Applicator certified? ***UNK***	Incident site: (examples include home, yard, school, industrial, nursery/greenhouse, surface water, commercial turf, building/office, forest/ woods, agricultural (specify crop) right-of-way (rail, utility, highway)). ***Own Residence***	Situation (act of using product): (examples include mixing/loading, reentry, application, transportation, repair/ maintenance of application equipment, manufacturing/ formulating). ***See Incident Description Notes***
	How exposed: (examples include direct contact with treated surface, ingestion, spill, drift, runoff) ***See Incident Description Notes***		

Personal privacy information

Brief description of incident circumstances.

Nordaune, Abby May 22 2012 6:42PM
Hx: [redacted] is calling on behalf of his girlfriend [redacted], her son [redacted], and her son's girlfriend [redacted]. Due to the complexity of the case he has somewhat limited / fragmented details of potential exposure histories. He is concerned about the recent use of this product in a camper and his own home and apparent seizure activity several people have had recently.

Caller states that [redacted] sprayed this product 4-5x over a two-week period of time about 2 months ago to the interior of a camper that he is living in. At the time of application, the windows were open in the camper to allow air flow / ventilation. This product was also sprayed twice over a two week period of time to the interior of [redacted] own home as well about 6 weeks ago.

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[redacted] is most worried about the seizure activity and link with the use of the product.

A: Discussed with SL –

There is no indication that the use of the product is at all linked with the reported health effects; it is difficult to determine that an actual exposure to the product at any concentration has even occurred other than simply residing in a home / structure that product had been sprayed in. Given the low concentration of the AI in product, even in the event that gross misuse of the product had occurred inhalation exposure to the product is not expected to result in such neurological effects and additionally, 2 of the 3 parties involved have at least a vague history of seizure activity in the past that cannot be discounted.

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* * * * * * * * * * * * * * * * *
LeMaster, Steve May 23 2012 10:50AM
notified client

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

<table>
<tr><td>Demographic information:
Age: 40 Year(s) Sex: Female
Occupation (if relevant)
NA</td><td>Exposure route:
Unknown route</td><td>Was adverse effect result of suicide/homicide or attempted suicide/homicide?
No</td><td rowspan="2">Was protective clothing worn (specify)?
None Reported</td></tr>
<tr><td>If female, pregnant?
NO</td><td>Was exposure occupational?
Not indicated
If yes, days lost due to illness:
NA</td><td>Time between exposure and onset of symptoms:
1 month or less</td></tr>
<tr><td>Type of medical care sought: (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient).
Private MD/DVM-treated & released</td><td colspan="2" rowspan="3">List signs/symptoms/adverse effects
Neurological-Seizure (single)</td><td rowspan="3">If lab tests were performed, list test names and results (If available, submit reports)
None Reported</td></tr>
<tr><td>Exposure data: NA
Amount of pesticide: NA
Exposure duration: Chronic: >1 month <= 3 months
Patient weight: Unknown</td></tr>
<tr><td>Human severity category:
HC</td></tr>
<tr><td colspan="4">This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary).

Internal ID #
978240-2</td></tr>
</table>

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Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

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Row 1 Administrative Data	Reporter Name [redacted]	Submission date. ***6/29/2012***	Contact person (if different than reporter)	Internal ID ***978240-3***
	Address [redacted]		Address	
	Phone # [redacted]		Phone #	
	Incident Status: ***New***	Location and date of incident ***Middleberg, FL USA Chronic: >1 month <= 3 months***	Date registrant became aware of incident. ***05/22/2012***	Was incident part of larger study? ***No***

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* * * * * * * * * * * * * * * * * *
LeMaster, Steve May 23 2012 10:50AM
notified client

Voluntary Industry Reporting Form for 6(a)(2) Adverse Effects Incident Information

Provide all known, required information. If required data field information is unknown, designate as such in appropriate area

Demographic information: Age: ***23 Year(s)*** Sex: ***Female*** Occupation (if relevant) ***NA***	Exposure route: ***Unknown route***	Was adverse effect result of suicide/homicide or attempted suicide/homicide? ***No***	Was protective clothing worn (specify)? ***None Reported***
If female, pregnant? ***NO***	Was exposure occupational? ***Not indicated*** If yes, days lost due to illness: ***NA***	Time between exposure and onset of symptoms: ***>1 month and <=3 months***	
Type of medical care sought: (examples include none, clinic, hospital emergency department, private physician, PCC, hospital inpatient). ***Private MD/DVM-treated & released***	List signs/symptoms/adverse effects ***Neurological-Seizure (single)***		If lab tests were performed, list test names and results (If available, submit reports) ***None Reported***
Exposure data: ***NA*** Amount of pesticide: ***NA*** Exposure duration: ***Chronic: >1 month <= 3 months*** Patient weight: ***Unknown***			
Human severity category: ***HC***			
This box can be used to provide any explanatory or qualifying information surrounding the incident. (add additional pages if necessary)			Internal ID # ***978240-3***